

Insurance & Coverage Considerations for MCD

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Disclosures

- ICER: Member of the California Technology Assessment Forum (CTAF), which is an independent appraisal committee for the Institute for Clinical and Economic Review (ICER)
- Chair, Global Economics and Evaluation of Clinical Genomics Sequencing Working Group, supported by Illumina Inc.

Questions

- 1) Why assess coverage considerations now - when clinical utility has not been demonstrated?
- 2) How do payers consider evidence needed for coverage?
- 3) What are possible next steps?

1) Why assess coverage considerations now - when clinical utility has not been demonstrated?

- After adoption into care is too late!
 - If coverage not considered/addressed early likely to lead to variable access & disparities
 - Complex pathway requires new frameworks & approaches
 - Coverage of test itself is only tip of iceberg
 - Need to consider coverage of:
 - Follow-up interventions: whether test negative or positive
 - Overlapping tests: whether/when will be covered
 - Repeated testing: Who? When?
- Simultaneously develop evidence:
 - Clinical utility
 - Payer evidentiary requirements – and data to address those
 - Data & modeling needed for assessing budget impact (“can pay”) & cost-effectiveness (“should” pay)
 - Patient & provider preferences and needs
 - How to avoid inequities



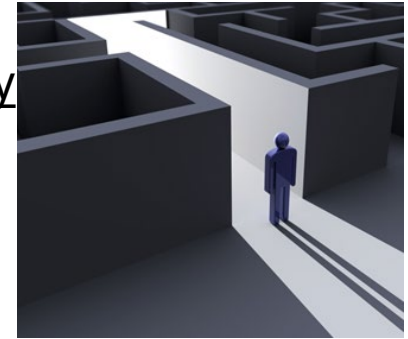
2) How do payers consider evidence needed for coverage?

- In-depth, descriptive studies with TRANSPERS Payer Advisory Board
 - Board established 2007
 - Senior executives representing largest national health plans, regional plans/integrated health systems, employer groups on health, lab benefit manager companies
 - > 10 peer-reviewed publications
- Study on MCD published 2023: 19 payers/organizations (150M lives)
 - 84% of payers saw potential merit of MCD for cancers w/o current screening
 - 42% viewed merit of MCD with existing screening
 - Common barriers noted
 - 71% inclusion of cancers w/o prior demonstration of benefit from early diagnosis
 - 53% high false-negative rate
 - 53% lack of care protocols for false-positive MCD tests
 - Majority (64%) would potentially accept rigorous RWE (vs. RCTs)
 - 58% would accept surrogate endpoints
 - Even if clinical benefits demonstrated, 58% would not cover MCD tests for general population 50+
 - Majority (74%) did not expect MCD to reduce disparities due to potential harm from overtreatment & barriers to downstream care



3) What are possible next steps?

- 1. Develop frameworks/approaches for considering coverage/protocols of entire pathway
 - Screening is a continuum – all components must be considered
 - Need to address need for comprehensive and consistent guidelines
 - NAM Roundtable on Genomics Workshop 10/29-10/30
- 2. Assess multiple possible coverage pathways
 - Medicaid & Medicare & private insurer – and self-insured employers and lab benefit managers
 - Coverage with evidence development/TCET & other performance-based risk sharing arrangements
 - State & national legislation
 - Our recent JAMA study found state legislation mandating payer coverage for “biomarker testing” is well-intentioned but there are implementation challenges
 - New Administration? LDT regulation?
- 3. Engage payers – and patients - in study design & dissemination
 - Involve patient advocacy groups
 - Engage payers



Deverka et al, Health Affairs, 2022

Trosman et al, Health Affairs Scholar, 2023

Lin et al, JAMA 2024

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Thank you!

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POLICY INSIGHT

Multicancer Screening Tests: Anticipating And Addressing Considerations For Payer Coverage And Patient Access

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[AFFILIATIONS](#) ✓

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> [JAMA](#). 2024 Jun 11;331(22):1885-1886. doi: 10.1001/jama.2024.6058.

The State of State Biomarker Testing Insurance Coverage Laws

[Grace A Lin](#) ^{1 2}, [Janet M Coffman](#) ², [Kathryn A Phillips](#) ^{1 2}

Perspectives of private payers on multicancer early- detection tests: informing research, implementation, and policy

[Julia R Trosman](#) , [Christine B Weldon](#), [Allison W Kurian](#), [Mary M Pasquinelli](#),
[Sheetal M Kircher](#), [Nikki Martin](#), [Michael P Douglas](#), [Kathryn A Phillips](#) [Author Notes](#)

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